A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

MAR 21 2013

K Number	K121979
Submitter Information	
Name	MEDICREA INTERNATIONAL
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Establishment registration Number	1000432246
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Date Prepared	March 20, 2013
Name of Device	
Trade or Proprietary Name	PASS OCT Spinal System
Common or Usual name	Spinal Fixation Appliances
Classification name and Reference	Spinal Interlaminal Fixation Orthosis 21 CFR 888.3050
Classification	Class II
Product code(s)	KWP: Appliance, Fixation, Spinal Interlaminal
Legally marketed device(s) to which equivalence is claimed	See table below
Device Description	The PASS OCT Spinal System is a posterior system, which consists of a variety of shapes and sizes of rods, hooks, polyaxial screws, occipital plates, occipital bone screws, and connecting components, which can be rigidly locked to the rod in a variety of configurations. See package insert of the system for labeling limitations. The implants are manufactured from titanium alloy Ti-6Al-4V ELI conforming to ISO 5832-3 specifications and ASTM F136 specifications and in PEEK OPTIMA LT1 conforming to ASTM F2026 specifications.

510(k) Number	Title	Date Cleared
K002733	Summit Occipito-Cervico-Thoracic (OCT) Spinal System	12/15/00
K042508	Mountaineer OCT Spinal System	7/10/04
K062136	PASS 2 Spinal System	6/10/06
K003780	Vertex Reconstruction System	9/28/01

	Never use stainless steel and titanium implant components in the same construct. To achieve best results, do not use any of the PASS OCT Spinal System implant components with components from any other systems or manufacturer unless specifically labeled to do so in this or another MEDICREA® INTERNATIONAL document. As with all orthopedic and neurosurgical implants, none of the PASS OCT Spinal components should ever be reused under any circumstances. **MATERIALS:** Titanium Alloy (Ti-6Al-4V) according to the ASTM F136-11 & ISO 5832-30 and PEEK OPTIMA LT1® according to the ASTM F2026-10.
Intended use of the device	MEDICREA® INTERNATIONAL PASS OCT implants are designed to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the occipital, cervical and/or upper thotacic spine (occiput-T3). These devices should not be used in the inferior thoracic, lumbar and sacral region. These implants are designed to stabilize the spine during normal development of solid bony consolidation. After this period the device is no longer strictly necessary and may be removed.
Indications for use	When intended to promote fusion of the occipitocervical spine, the cervical spine, and the upper-thoracic spine (Occiput-T3), the PASS OCT Spinal System is intended for: - Degenerative Disc Disease (DDD): neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies. - Spondylolisthesis - Spinal Stenosis - Trauma (i.e. Fracture or Dislocation) - Atlanto/axial fracture with instability - Revision of previous cervical spine surgery - Tumors <u>Occipital Plates / Occipital Bone Screws / Hooks:</u> The occipital plates, occipital bone screws, and hooks are intended to provide stabilization and to promote fusion in the occipitocervical junction and the cervical spine. When used to treat these occipitocervical and cervical conditions, the occipital bone screws are limited to occipital fixation only. The use of the occipital plate requires bilateral fixation to C2 and below. Note: segmental fixation is recommended for these constructs. <u>Hooks and rods:</u> The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine. <u>Polyaxial screws/Connectors:</u> The use of the polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) for anchoring the OCT construct, and are not intended to treat thoracic conditions. The polyaxial screws are not intended to be placed in the cervical spine. The PASS OCT Spinal System can also be linked to the PASS LP® Spinal System using the dual diameter rod.

Performance Data	
SUMMARY OF NON-CLINICAL TEST CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE	
Performance test Summary-New Device	
Characteristic	*Standard/Test/FDA Guidance*
Multi-axial screws & Rods Constructs	
Static Compression	ASTM F2706-08 / Guidance of Spinal System 510(k)s
Dynamic Compression	ASTM F2706-08 / Guidance of Spinal System 510(k)s
Static Torsion	ASTM F2706-08 / Guidance of Spinal System 510(k)s
Occipital Plates, Occipital Screws & Dual Diameter Rod Constructs	
Static Compression	ASTM F2706-08 / Guidance of Spinal System 510(k)s
Dynamic Compression	ASTM F2706-08 / Guidance of Spinal System 510(k)s
Static Torsion	ASTM F2706-08 / Guidance of Spinal System 510(k)s
Dynamic Torsion	ASTM F2706-08 / Guidance of Spinal System 510(k)s
SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION	
Not Applicable	
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA	
MEDICREA® INTERNATIONAL PASS OCT Spinal system is substantially equivalent to the SUMMIT System (K002733), the Mountaineer OCT Spinal System (K042508), the Vertex Reconstruction System (K052734), in terms of intended use, materials used, design, mechanical safety and performances. And MEDICREA® INTERNATIONAL PASS OCT Spinal system is substantially equivalent to the PASS 2 Spinal System (K062136) in terms of materials used and design. The MEDICREA® INTERNATIONAL PASS OCT Spinal System is safe and effective and performs as well as the predicates SUMMIT Spinal System (K041203), the Mountaineer OCT Spinal System (K042508), the Vertex Reconstruction System (K52734), and the PASS 2 Spinal System (K062136).	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 21, 2013

Medicrea International
% Ms. Audrey Vion
Regulatory Affairs Manager
14 Porte du Grand Lyon
01700 Neyron
France

Re: K121979
Trade/Device Name: PASS OCT Spinal System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: January 16, 2013
Received: February 15, 2013

Dear Ms. Vion:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K121979

Device Name: PASS OCT Spinal System

When intended to promote fusion of the occipitocervical spine, the cervical spine, and the upper-thoracic spine (Occiput-T3), the PASS OCT Spinal System is intended for:

- Degenerative Disc Disease (DDD): neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies.
- Spondylolisthesis
- Spinal Stenosis
- Trauma (i.e. Fracture or Dislocation)
- Atlanto/axial fracture with instability
- Revision of previous cervical spine surgery
- Tumors

Occipital Plates / Occipital Bone Screws / Hooks:
The occipital plates, occipital bone screws, and hooks are intended to provide stabilization and to promote fusion in the occipitocervical junction and the cervical spine. When used to treat these occipitocervical and cervical conditions, the occipital bone screws are limited to occipital fixation only.
The use of the occipital plate requires bilateral fixation to C2 and below.
Note: segmental fixation is recommended for these constructs.

Hooks and rods:
The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

Polyaxial screws/Connectors:
The use of the polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) for anchoring the OCT construct, and are not intended to treat thoracic conditions. The polyaxial screws are not intended to be placed in the cervical spine.

The PASS OCT Spinal System can also be linked to the PASS LP® Spinal System using the dual diameter rod.

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Erin I. Keith

Division of Orthopedic Devices